CENTER for BIOLOGICAL DIVERSITY Because life is good.

May 14, 2018

VIA FOIAONLINE.REGULATIONS.GOV
U.S. Environmental Protection Agency

Re: Freedom of Information Act Request: New Pesticide BEs for Genetically Modified Crops

Dear FOIA Officer:

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, *as amended* ("FOIA"), from the Center for Biological Diversity ("Center"), a non-profit organization that works to secure a future for all species hovering on the brink of extinction through science, law, and creative media, and to fulfill the continuing educational goals of its membership and the general public in the process.

REQUESTED RECORDS

The Center requests from the U.S. Environmental Protection Agency ("EPA"), Office of Pesticide Programs Environmental Fate and Effects Division: the records generated in connection to the preparation of biological evaluations for new pesticide products registered for use on genetically modified crops, as discussed in Marietta Echeverria's, paragraph 19. Attachment A (Marietta Echeverria's Declaration).

For this request, the term "records" refers to, but is not limited to, any and all documents, correspondence (including, but not limited to, inter and/or intra-agency correspondence as well as correspondence with entities or individuals outside the federal government), emails, letters, notes, recordings, telephone records, voicemails, telephone notes, telephone logs, text messages, chat messages, minutes, memoranda, comments, files, presentations, consultations, biological opinions, assessments, evaluations, schedules, papers published and/or unpublished, reports, studies, photographs and other images, data (including raw data, GPS or GIS data, UTM, LiDAR, etc.), maps, and/or all other responsive records, in draft or final form.

This request is not meant to exclude any other records that, although not specially requested, are reasonably related to the subject matter of this request. If you or your office have destroyed or determine to withhold any records that could be reasonably construed to be responsive to this request, I ask that you indicate this fact and the reasons therefore in your response.

Under the FOIA Improvement Act of 2016, agencies are prohibited from denying requests for information under FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption. FOIA Improvement Act of 2016 (Public Law No. 114-185), codified at 5 U.S.C. § 552(a)(8)(A).

Alaska · Arizona · California · Florida · Minnesota · Nevada · New Mexico · New York · Oregon · Vermont · Washington, DC
P.O. Box 710 · Tucson, AZ 85702-0710 tel: (520) 623.5252 fax: (520) 623.9797 www.BiologicalDiversity.org

If you decide to invoke a FOIA exemption, please include sufficient information for us to assess the basis for the exemption, including any interest(s) that would be harmed by release. Please include a detailed ledger which includes:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item; and

2. Complete explanations and justifications for the withholding, including the specific exemption(s) under which the record (or portion thereof) was withheld and a full explanation of how each exemption applies to the withheld material. Such statements will be helpful in deciding whether to appeal an adverse determination. Your written justification may help to avoid litigation.

If you determine that portions of the records requested are exempt from disclosure, we request that you segregate the exempt portions and mail the non-exempt portions of such records to my attention at the address below within the statutory time limit. 5 U.S.C. § 552(b).

The Center is willing to receive records on a rolling basis.

Finally, FOIA's "frequently requested record" provision was enacted as part of the 1996 Electronic Freedom of Information Act Amendments, and requires all federal agencies to give "reading room" treatment to any FOIA-processed records that, "because of the nature of their subject matter, the agency determines have become the subject of subsequent requests for substantially the same records." *See* 5 U.S.C. § 552(a)(2)(D)(ii)(I). Also, enacted as part of the 2016 FOIA Improvement Act, FOIA's Rule of 3 requires all federal agencies to proactively "make available for public inspection in an electronic format" "copies of records, regardless of form or format … that have been released to any person … and … that have been requested 3 or more times." 5 U.S.C. § 552(a)(2)(D)(ii)(II). Therefore, we respectfully request that you make available online any records that the agency determines will become the subject of subsequent requests for substantially the same records, and records that have been requested three or more times.

FORMAT OF REQUESTED RECORDS

Under FOIA, you are obligated to provide records in a readily accessible electronic format and in the format requested. *See, e.g.,* 5 U.S.C. § 552(a)(3)(B) ("In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format."). "Readily accessible" means text-searchable and OCR-formatted. *See* 5 U.S.C. § 552(a)(3)(B). Pursuant to this requirement, we hereby request that you produce all records in an electronic format and in their native file formats. Additionally, please provide the records in a load-ready format with a CSV file index or Excel spreadsheet. If you produce files in .PDF format, then please omit any "portfolios" or "embedded files." Portfolios and embedded files within files are not readily accessible. Please do not provide the records in a single, or "batched," .PDF file. We appreciate the inclusion of an index.

If you should seek to withhold or redact any responsive records, we request that you: (1) identify each such record with specificity (including date, author, recipient, and parties copied); (2) explain in full the basis for withholding responsive material; and (3) provide all segregable portions of the records for which you claim a specific exemption. 5 U.S.C. § 552(b). Please correlate any redactions with specific exemptions under FOIA.

RECORD DELIVERY

We appreciate your help in expeditiously obtaining a determination on the requested records. As mandated in FOIA, we anticipate a reply within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). Failure to comply within the statutory timeframe may result in the Center taking additional steps to ensure timely receipt of the requested materials. Please provide a complete reply as expeditiously as possible. You may email or mail copies of the requested records to:

Margaret E. Townsend
Center for Biological Diversity
P.O. Box 11374
Portland, OR 97211
foia@biologicaldiversity.org

If you find that this request is unclear, or if the responsive records are voluminous, please email me to discuss the scope of this request.

REQUEST FOR FEE WAIVER

FOIA was designed to provide citizens a broad right to access government records. FOIA's basic purpose is to "open agency action to the light of public scrutiny," with a focus on the public's "right to be informed about what their government is up to." *U.S. Dep't of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 773-74 (1989) (internal quotation and citations omitted). In order to provide public access to this information, FOIA's fee waiver provision requires that "[d]ocuments shall be furnished without any charge or at a [reduced] charge," if the request satisfies the standard. 5 U.S.C. § 552(a)(4)(A)(iii). FOIA's fee waiver requirement is "liberally construed." *Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1310 (D.C. Cir. 2003); *Forest Guardians v. U.S. Dept. of Interior*, 416 F.3d 1173, 1178 (10th Cir. 2005).

The 1986 fee waiver amendments were designed specifically to provide non-profit organizations such as the Center access to government records without the payment of fees. Indeed, FOIA's fee waiver provision was intended "to prevent government agencies from using high fees to discourage certain types of requesters and requests," which are "consistently associated with requests from journalists, scholars, and *non-profit public interest groups*." *Ettlinger v. FBI*, 596 F.Supp. 867, 872 (D. Mass. 1984) (emphasis added). As one Senator stated, "[a]gencies should not be allowed to use fees as an offensive weapon against requesters seeking access to Government information ... ." 132 Cong. Rec. S. 14298 (statement of Senator Leahy).

I. The Center Qualifies for a Fee Waiver.

Under FOIA, a party is entitled to a fee waiver when "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the [Federal] government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). EPA's regulations at 40 C.F.R. § 2.107(l)(1)-(3) establish the same standard.

Thus, EPA must consider four factors to determine whether a request is in the public interest: (1) whether the subject of the requested records concerns "the operations or activities of the Federal government," (2) whether the disclosure is "likely to contribute" to an understanding of government operations or activities, (3) whether the disclosure "will contribute to public understanding" of a reasonably broad audience of persons interested in the subject, and (4) whether the disclosure is likely to contribute "significantly" to public understanding of government operations or activities. 40 C.F.R. § 2.107(1)(2). As shown below, the Center meets each of these factors.

A. The Subject of This Request Concerns "The Operations and Activities of the Government."

The subject matter of this request concerns the operations and activities of the EPA. This request asks for the records generated in connection to the preparation of biological evaluations for new pesticide products registered for use on genetically modified crops, as discussed in Marietta Echeverria's, paragraph 19. Attachment A.

This FOIA will provide the Center and the public with crucial insight into EPA's preparation of biological evaluations for new pesticide products. It is clear that a federal agency's registration of toxic pesticides is a specific and identifiable activity of the government, in this case the executive branch agency, EPA. *Judicial Watch*, 326 F.3d at 1313 ("[R]easonable specificity is all that FOIA requires with regard to this factor") (internal quotations omitted). Thus, the Center meets this factor.

B. Disclosure is "Likely to Contribute" to an Understanding of Government Operations or Activities.

The requested records are meaningfully informative about government operations or activities and will contribute to an increased understanding of those operations and activities by the public.

Disclosure of the requested records will allow the Center to convey to the public information about the comments made in the "Declaration of Marietta Echeverria," where she states:

> In addition to these commitments, my staff also must conduct other ESA assessments to support OPP pesticide registration activities. While the matters I have mentioned above make up the largest portion of OPP's current ESA work, EFED is also engaged in developing BEs for new pesticide products registered for

use on genetically modified crops and working to help defend litigation associated with the approval of such products.

Attachment A. Once the information is made available, the Center will analyze it and present it to its 1.6 million members and online activists and the general public in a manner that will meaningfully enhance the public's understanding of this topic.

Thus, the requested records are likely to contribute to an understanding of EPA operations and activities.

C. Disclosure of the Requested Records Will Contribute to a Reasonably Broad Audience of Interested Persons' Understanding of New Pesticides for Genetically Modified Crops

The requested records will contribute to public understanding of whether EPA's actions concerning new pesticide registration is consistent with EPA's mission "to protect human health and the environment."[1] As explained above, the records will contribute to public understanding of this topic.

Activities of EPA generally, and specifically its biological evaluations of new pesticide products registered for use on genetically modified crops are areas of interest to a reasonably broad segment of the public. The Center will use the information it obtains from the disclosed records to educate the public at large about this subject matter. *See W. Watersheds Proj. v. Brown*, 318 F.Supp.2d 1036, 1040 (D. Idaho 2004) ("... find[ing] that WWP adequately specified the public interest to be served, that is, educating the public about the ecological conditions of the land managed by the BLM and also how … management strategies employed by the BLM may adversely affect the environment.").

Through the Center's synthesis and dissemination (by means discussed in Section II, below), disclosure of information contained in and gleaned from the requested records will contribute to a broad audience of persons who are interested in the subject matter. *Ettlinger v. FBI*, 596 F.Supp. at 876 (benefit to a population group of some size distinct from the requester alone is sufficient); *Carney v. Dep't of Justice*, 19 F.3d 807, 815 (2d Cir. 1994), *cert. denied*, 513 U.S. 823 (1994) (applying "public" to require a sufficient "breadth of benefit" beyond the requester's own interests); *Cmty. Legal Servs. v. Dep't of Hous. & Urban Dev.*, 405 F.Supp.2d 553, 557 (E.D. Pa. 2005) (in granting fee waiver to community legal group, court noted that while the requester's "work by its nature is unlikely to reach a very general audience," "there is a segment of the public that is interested in its work").

Indeed, the public does not currently have an ability to easily evaluate the requested records, which concern new pesticide products that are not currently in the public domain. *See Cmty. Legal Servs. v. HUD*, 405 F.Supp.2d 553, 560 (D. Pa. 2005) (because requested records "clarify important facts" about agency policy, "the CLS request would likely shed light on information

[1] EPA, Our Mission and What We Do: Our Mission, https://www.epa.gov/aboutepa/our-mission-and-what-we-do (last visited May 14, 2018).

that is new to the interested public."). As the Ninth Circuit observed in *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1286 (9th Cir. 1987), "[FOIA] legislative history suggests that information [has more potential to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations… ."[2]

Disclosure of these records is not only "likely to contribute," but is certain to contribute, to public understanding of biological evaluations concerning new pesticide products. The public is always well served when it knows how the government conducts its activities, particularly matters touching on legal questions. Hence, there can be no dispute that disclosure of the requested records to the public will educate the public about this topic.

D. Disclosure is Likely to Contribute Significantly to Public Understanding of Government Operations or Activities.

The Center is not requesting these records merely for their intrinsic informational value. Disclosure of the requested records will significantly enhance the public's understanding of the preparation of biological evaluations for new pesticides, as compared to the level of public understanding that exists prior to the disclosure. Indeed, public understanding will be *significantly* increased as a result of disclosure because the requested records will help reveal more about this subject matter.

The records are also certain to shed light on EPA's compliance with its own mission.[3] Such public oversight of agency action is vital to our democratic system and clearly envisioned by the drafters of the FOIA. Thus, the Center meets this factor as well.

II. The Center has a Demonstrated Ability to Disseminate the Requested Information Broadly.

The Center is a non-profit organization that informs, educates, and counsels the public regarding environmental issues, policies, and laws relating to environmental issues. The Center has been substantially involved in the activities of numerous government agencies for over 25 years, and has consistently displayed its ability to disseminate information granted to it through FOIA.

In consistently granting the Center's fee waivers, agencies have recognized: (1) that the information requested by the Center contributes significantly to the public's understanding of the government's operations or activities; (2) that the information enhances the public's understanding to a greater degree than currently exists; (3) that the Center possesses the expertise to explain the requested information to the public; (4) that the Center possesses the ability to disseminate the requested information to the general public; (5) and that the news media recognizes the Center as an established expert in the field of imperiled species, biodiversity, and

[2] In this connection, it is immaterial whether any portion of the Center's request may currently be in the public domain because the Center requests considerably more than any piece of information that may currently be available to other individuals. *See Judicial Watch*, 326 F.3d at 1315.

[3] *See supra* note 1.

impacts on protected species. The Center's track record of active participation in oversight of governmental activities and decision making, and its consistent contribution to the public's understanding of those activities as compared to the level of public understanding prior to disclosure are well established.

The Center intends to use the records requested here similarly. The Center's work appears in more than 2,500 news stories online and in print, radio and TV per month, including regular reporting in such important outlets as *The New York Times*, *Washington Post*, *The Guardian*, and *Los Angeles Times*. Many media outlets have reported on the effects of pesticides to environmental and human health utilizing information obtained by the Center from federal agencies, including EPA. In 2017, more than 2.7 million people visited the Center's extensive website, and viewed pages a total of 5.7 million times. The Center sends out more than 277 email newsletters and action alerts per year to more than 1.6 million members and supporters. Three times a year, the Center sends printed newsletters to more than 63,000 members. More than 304,800 people have "liked" the Center on Facebook, and there are regular postings regarding environmental protection. The Center also regularly tweets to more than 57,900 followers on Twitter. The Center intends to use any or all of these far-reaching media outlets to share with the public information obtained as a result of this request.

Public oversight and enhanced understanding of EPA's duties is absolutely necessary. In determining whether disclosure of requested information will contribute significantly to public understanding, a guiding test is whether the requester will disseminate the information to a reasonably broad audience of persons interested in the subject. *Carney v U.S. Dept. of Justice*, 19 F.3d 807 (2nd Cir. 1994). The Center need not show how it intends to distribute the information, because "[n]othing in FOIA, the [agency] regulation, or our case law require[s] such pointless specificity." *Judicial Watch*, 326 F.3d at 1314. It is sufficient for the Center to show how it distributes information to the public generally. *Id.*

III. Obtaining the Requested Records is of No Commercial Interest to the Center.

Access to government records, disclosure forms, and similar materials through FOIA requests is essential to the Center's role of educating the general public. Founded in 1994, the Center is a 501(c)(3) nonprofit conservation organization (EIN: 27-3943866) with more than 1.6 million members and online activists dedicated to the protection of endangered and threatened species and wild places. The Center has no commercial interest and will realize no commercial benefit from the release of the requested records.

IV. Conclusion

For all of the foregoing reasons, the Center qualifies for a full fee waiver. We hope that EPA will immediately grant this fee waiver request and begin to search and disclose the requested records without any unnecessary delays.

If you have any questions, please contact me at foia@biologicaldiversity.org. All records and any related correspondence should be sent to my attention at the address below.

Sincerely,

Margaret E. Townsend
Open Government Staff Attorney
CENTER FOR BIOLOGICAL DIVERSITY
P.O. Box 11374
Portland, OR 97211-0374
foia@biologicaldiversity.org

Attachment

Attachment A (Marietta Echeverria's Declaration)

Attachment A

JEFFREY H. WOOD
Acting Assistant Attorney General
Environment and Natural Resources Division
U.S. Department of Justice
John H. Martin, Colo. Bar No. 32667
Wildlife & Marine Resources Section
999 18th St., South Terrace Suite 370
Denver, CO 80202
(303) 844-1383 (tel)
(303) 844-1350 (fax)
Email: john.h.martin@usdoj.gov

Attorneys for Defendants

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

STEVE ELLIS, *et al.*, *Plaintiffs*, v. RICHARD P. KEIGWIN, JR., *et al.*, *Defendants*, and BAYER CROPSCIENCE, LP, *et al.*, *Defendant-Intervenors*.	Case No. 3:13-cv-01266-MMC Declaration of Marietta Echeverria

DECLARATION OF MARIETTA ECHEVERRIA

I, Marietta Echeverria, state the following:

1. I declare that the following statements are true and correct to the best of my knowledge and belief and are based on my personal knowledge, my experience over the course of my career, or my review of information contained in the records provided to this Court or evaluations of such records supplied by current U.S. Environmental Protection Agency ("EPA" or the "Agency") employees.

2. I am the Director of the Environmental Fate and Effects Division ("EFED") in EPA's Office of Pesticide Programs ("OPP"). I have worked for EPA for 15 years. I have served in various positions within EPA, including Physical Scientist, Team Leader, and Branch Chief in EFED; and Senior Advisor and Branch Chief in the Registration Division ("RD"). I have been the Director of EFED since November 2016.

3. EFED is the division assigned with the responsibility for assessing the ecological risk and environmental fate of both new and existing conventional pesticides under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). Part of this responsibility includes evaluating effects to species listed as threatened or endangered ("listed species") under the Endangered Species Act ("ESA") and preparing the biological evaluations ("BEs") that EPA provides to the National Marine Fisheries Service ("NMFS") and the United States Fish and Wildlife Service ("FWS") (collectively "Services") when it consults with the Services on pesticide actions that "may affect" listed species or their designated critical habitats. EPA's consultation obligations under the ESA involve extremely complex scientific assessments because rather than addressing effects of a discrete project at a specific location, EPA's pesticide registration actions effectively address the entire United States and therefore involve evaluation of the potential for effects to hundreds of listed species in numerous and varying aquatic and terrestrial habitats. In my roles as a supervisor, a scientist within EFED, and now as the Director, I have been involved in developing BEs, engaging with the Services in our ongoing ESA consultations, and overseeing the allocation of EFED resources necessary to conduct the ecological and environmental fate assessments of pesticides that are necessary for EPA to address its obligations under both FIFRA and the ESA.

4. This purpose of this declaration is to explain (1) how EPA develops BEs of the effects of pesticides on threatened and endangered species and how those evaluations differ from EPA's screening level risk assessments cited by Plaintiffs in their opening remedy brief; (2) why the Services need BEs that include detailed species-specific assessments utilizing EPA's expertise -- based on a comprehensive review of the best available scientific and commercial information -- before they can develop biological opinions for specific agency actions; and (3) EPA's estimated timeline for conducting BEs for products containing clothianidin and thiamethoxam, including but not limited to the 59 discrete pesticide product

decisions at issue in this case, and why that timeline is appropriate in light of the complexity and magnitude of the undertaking and the competing obligations, including those stemming from litigation, that EPA must also address.

5. Under section 7(a)(2) of the ESA, federal "action agencies" such as EPA are required to consult with the Services to insure that their actions are not likely to jeopardize listed species or destroy or adversely modify any designated critical habitat for such species. In advance of any formal consultation, under the Services' implementing consultation regulations at 50 C.F.R. sections 402.14 and 402.40-.48, action agencies have the initial obligation to determine whether their actions "may affect" listed species or habitat, in which case consultation is required, or will have "no effect" on listed species or habitat. EPA's BEs contain the agency's decisions and supporting analysis as to whether an EPA action may affect, or will have no effect, on listed species or habitat. The BE is not limited to a simple summary "may affect" finding. A BE is a comprehensive document that presents EPA's analysis of the manner in which the action may affect a species or habitat, along with detailed descriptions of the species, habitats, and geographic areas that may be affected and its reviews of the best available scientific and commercial information, relevant biological studies and literature reviews. EPA must present this comprehensive analysis in order to properly support a request to initiate formal consultation or request the Service's concurrence to conclude an informal consultation. See, e.g., 50 C.F.R. 402.14(c) and 402.40(b) (counterpart regulations governing actions under FIFRA).

6. Over the past 15 years, EPA and the Services have engaged in two significant efforts to jointly develop methodologies for assessing the effects of pesticides on listed species and critical habitat under the Service consultation regulations discussed above. The first effort, undertaken from 2002-2004, resulted in the development of counterpart Service consultation regulations (50 C.F.R. Part 402, subpart D) for pesticide registrations actions under FIFRA, and an accompanying EPA document entitled, Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency -- Endangered and Threatened Species Effects Determinations (Overview Document), available at https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf, which

outlined the approach EPA generally intended to take to conduct BEs on pesticide registration actions under FIFRA.

7. EPA's efforts to implement the Overview Document often resulted in disagreements between EPA and Service staff over methodological approaches. Among other issues, EPA and Service staff frequently took differing views on what constitutes the best available data, the proper evaluation of pesticide mixtures, the use of toxicity thresholds for effects determinations, incorporation of sublethal effects endpoints, the use of data on "surrogate" species, and the appropriate use and interpretation of exposure and risk modeling, among other fundamental issues of risk assessment for pesticides. These disagreements ultimately resulted in numerous stalled consultations, giving rise to litigation against the Services.

8. In an effort to resolve this consultation impasse, in 2011 EPA, the Services, and U.S. Department of Agriculture commissioned the National Academy of Sciences (NAS) to develop a report to provide recommendations to the agencies for improving the scientific approaches used at all stages of the consultation process on pesticide actions under FIFRA. In April 2013, the NAS issued its report, entitled, Assessing Risks to Endangered and Threatened Species from Pesticides (available at https://www.nap.edu/read/18344/chapter/1), which recommended a detailed, three-step process for EPA and the Services to follow to improve the consultation process on pesticides. The report tackled the prime areas of disagreement between EPA and the Services as outlined above, and gave the agencies a framework for an approach for coming to agreement on how best to address these areas. Following the release of the NAS report, EPA and the Services began work to develop shared scientific approaches, known as "the interim approaches," that reflect the advice provided by NAS. EPA and the Services identified a number of "pilot" consultations that could be completed using the interim approaches. EPA and the Services intend the pilot consultations to provide the agencies a focused opportunity to jointly refine and further develop the methodologies and build an efficient and effective approach to consultation that can be used in the future to address ESA compliance for EPA's FIFRA registration decisions.

9. In sum, the interim approaches call for EPA and the Services to track the three-step approach outlined by the NAS. See Interim Approaches for National-Level Pesticide

Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report, available at https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf. In step 1, EPA determines whether a pesticide will have no effect or may affect any listed species or critical habitat. In step 2, EPA determines whether the pesticide is or is not likely to adversely affect listed species or critical habitat. Once EPA completes step two, EPA then initiates any necessary formal or informal consultation. In Step 3, the Services determine, based on EPA's BE developed as part of Step 1 and Step 2, whether those species and habitats that are likely to be adversely affected are likely to be jeopardized or adversely modified by the action.

10. In conducting Step 1, EPA evaluates the potential overlap of the pesticide registration action area with the species' ranges and critical habitats. To undertake this task, EPA must evaluate multiple nationwide geospatial data sets to establish agricultural and non-agricultural pesticide use areas. EPA also considers water, spray drift and other off-site transport models for pesticides to determine the extent to which the action area should extend to areas surrounding potential treatment sites. Finally, EPA then considers the relationship of the action area to available species range and designated critical habitat geospatial information (including information from the Services, pesticide registrants and other potential sources including information developed by non-governmental organizations). In Step 2, EPA uses many of the same exposure and toxicity tools and databases used in Step 1 to determine whether species or habitats are likely to be adversely affected. In Step 2, however, EPA only considers toxicity and exposure endpoints relevant to the specific listed species and habitats being assessed.

11. Currently, EPA and the Services are piloting the interim approaches on the FIFRA registration review of products containing three organophosphate pesticides -- chlorpyrifos, diazinon and malathion -- and in the coming years plan to apply the methodologies to products containing six additional pesticides -- carbaryl, methomyl, atrazine, simazine, propazine and glyphosate. For all other ESA assessments, EPA is currently using the process described in the 2004 Overview Document, discussed above in paragraph six, until such time as the pilot process for the interim approaches is complete and yields a refined

consultation methodology that EPA and the Services agree will improve the ESA consultation process for FIFRA decisions.

12. The Plaintiffs' opening remedy brief includes multiple references to EPA's screening level risk assessments for clothianidin and thiamethoxam, issued both in connection with the evaluation of the original registrations of these pesticides and for consideration of subsequent applications for "new uses," to support their assertion that in many instances EPA has already made "may affect" determinations for listed species that compel EPA to initiate consultation rather than complete the BE process outlined above. See Plaintiffs' Opening Remedy Brief at 3-5. For example, they suggest that EPA has made a may affect determination for clothianidin seed coatings for corn and canola because EPA "concluded that 'the Agency's level of concern for endangered and threatened birds, mammals and non-target insects is exceeded for the proposed use of clothianidin on corn and canola.'" Id. at 3 (quoting EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola at AR43540). Plaintiffs appear to have misunderstood the nature of EPA's tiered risk assessment process and how it differs from an effects determination. EPA has not in fact completed effects determinations for these pesticides using either the methodologies set forth in the 2004 Overview Document or using the interim approaches that EPA and the Services are currently developing through several pilot consultations that are outlined above in paragraphs 8-11.

13. In a recent registration decision, EPA explained the difference between its screening level assessments and the development of an effects determination under the ESA under the 2004 Overview Document:

> The agency begins with a screening-level assessment that includes a basic ecological risk assessment based on its 2004 Overview of the Ecological Risk Assessment Process document. That assessment uses broad default assumptions to establish estimated environmental concentrations of particular pesticides. If the screening-level assessment results in a determination that no [levels of concern ("LOCs")] are exceeded, then the EPA concludes its analysis. On the other hand, where the screening-level assessment does not rule out potential effects (exceedances of any LOC) based on the broad default assumptions, the EPA then uses increasingly specific methods and exposure models to refine its estimated environmental exposures. At each screening step, the EPA compares the more refined exposures to the toxicity of the pesticide active ingredient to determine whether the pesticide exceeds LOCs (citation omitted) established for listed aquatic and terrestrial species. The EPA determines that there is no effect on listed species if, at any step in the screening-level assessment, no LOCs are exceeded. If, after performing all of the steps in the screening-level assessment, a pesticide still exceeds the agency's levels of

> concern for listed species, the EPA then conducts a species-specific refined assessment to make effects determinations for individual listed species. The refined assessment, unlike the screening-level assessment, takes account of species' habitats and behaviors to determine whether any listed species may be affected by use of the pesticide.

See Final Registration of Enlist Duo Herbicide at 17-18.[1] In sum, EPA's conclusions in the screening level risk assessments cited by Plaintiffs that endangered species levels of concern are exceeded for certain taxa are not effect determinations for any specific species, but rather, represent a determination that EPA must conduct species-specific assessments in order to determine which, if any, species and habitats across the country may be affected by the action. Because EPA has not completed species-specific assessments for clothianidin and thiamethoxam, that work must be completed before EPA can provide a BE to the Services to initiate consultation.

14. Plaintiffs also point to several places in EPA's clothianidin and thiamethoxam risk assessment documents where they assert that EPA has in fact reached risk conclusions for specific endangered species. For example, Plaintiffs cite EPA's risk assessment for thiamethoxam on rice, noting that "EPA found a total of twelve protected species may be affected." Plaintiffs' Opening Remedy Brief at 5, citing AR 42404. While EPA understands why the statements in that risk assessment could be mistaken to be an EPA effects determination with respect to those species, the cited assessment is a screening level assessment that did not in fact evaluate a comprehensive suite of species-specific attributes, such as habitat and behavior, to reach a conclusion whether and how these species may be affected by the rice use of thiamethoxam. The 12 species identified in the referenced thiamethoxam assessment were identified using the LOCATES tool. LOCATES identifies species that are in the same county as rice production. The potential for those species to be affected by thiamethoxam was based on an exceedance of the LOC for the broad taxonomic group of the species (e.g., birds) or their dietary items. Additional analyses were not conducted to determine if the 12 species: (1) are likely to be in or in close proximity to rice paddies, or (2) if their specific biological and ecological characteristics are consistent with

---

[1] Available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0594-0660

species that could be at risk from use of thiamethoxam on rice. Current interim methodology for a BE would include such an analysis. In addition, the referenced thiamethoxam assessment was conducted to support a decision of whether or not to approve an emergency exemption under Section 18 of FIFRA (7 U.S.C. section 136p) for drill-seeded rice in Arkansas. Given the need for EPA to respond quickly to an emergency request, these types of assessments are expedited, screening level reviews that include broad default assumptions regarding the potential for exposure. For example, in this assessment EPA used a screening-level rice model to estimate aquatic exposures in a rice paddy, which assumes that 100% of the applied pesticide mass is available to be in the paddy water. No estimates were made to account for the mass of chemical that remains on/in the seed or buried under the soil, resulting in lower potential exposures, and estimated concentrations of thiamethoxam outside of the rice paddy were not calculated. Also, BEs evaluate the potential for a pesticide to indirectly affect federally listed species by potentially impacting food availability or habitat. In the referenced thiamethoxam assessments, the potential for indirect effects was noted when there was an LOC exceedance for food items of listed species (for example, effects to aquatic invertebrates for fish that may consume them). However, more specific dietary considerations specific for each species would be evaluated in a BE that were not considered in the Section 18 emergency exemption assessment. This type of assessment is necessary to conduct an effects determination.

15. Because risk assessments prepared by EFED to support either a proposed new use of a pesticide or to support an emergency exemption under FIFRA are typically screening level assessments, they lack the specificity and scope to support the consultation process and a biological opinion. The recent Biological Evaluations conducted for three organophosphate insecticides include considerably more data and analyses than what is in the referenced assessments for thiamethoxam and clothianidin. Indeed, the three organophosphate BEs each exceeded 10,000 pages in length and included the following:

- A robust spatial overlap analysis that determines exposure potential;
- A quantitative exposure analyses that represent a variety of different environments;
- Species sensitivity distributions that define the variability of sensitivities of species to toxicity endpoints;

- Consideration of specific species habitat, diet, and biological characteristics, as they relate to an individual species' potential to be exposed and relevancy of the effects observed in toxicity studies; and
- An evaluation of open literature.

These BEs are available at https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and. The risk assessment documents Plaintiffs reference may identify taxonomic groups such as birds, mammals, plants, and insects that may be at risk; however, the specific biological, behavioral, and physical characteristics of unique threatened and endangered species are not considered in EFED's FIFRA assessments to support proposed new use and emergency exemption registration requests. Indeed, EPA attempts to initiate consultation using assessments that are more comprehensive than those cited by Plaintiffs have been criticized by the Services as insufficient to support a biological opinion for reasons described in Paragraph 7 of this declaration. See Exhibit 1 (Jan. 14, 2009 letter from Marjorie A. Nelson to Arthur-Jean B. Williams requesting that EPA provide additional information to FWS to initiate formal consultation). In sum, in order to determine if particular threatened and endangered species may be exposed to and affected by a particular pesticide, additional analyses are needed and that information would need to be compiled, evaluated, and included in a robust biological evaluation in order to support a biological opinion to be conducted by the Services in the consultation process.

16. It also important to note that since the development of the screening level risk assessments cited by plaintiffs, EPA has received and evaluated a considerable body of new data and literature that will bear on the development of BEs for these pesticides. Indeed, on December 21, 2017, EPA published for 60 days' public comment draft ecological risk assessments for the registration review of both pesticides that take into consideration a wide array of new information that was not available and therefore not considered in developing the screening level assessments cited by plaintiffs. Both draft risk assessments are available for review at https://www.epa.gov/pesticides/epa-releases-neonicotinoid-assessments-public-comment. Those draft risk assessments also make clear that they do not represent or include effects determinations on listed species and that EPA completion of BEs for these two

neonicotinoid pesticides would follow upon the completion of the interim approaches being developed in the current pilot consultations:

> Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological problem formulation supporting the Preliminary Work Plan for clothianidin does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. While the agencies continue to develop a common method for ESA analysis, the planned risk assessment for the registration review of clothianidin will describe the level of ESA analysis completed for this particular registration review case. This assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists, once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses of clothianidin as part of completing this registration review.

Clothianidin – Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review at 105. See also Thiamethoxam -Transmittal of the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support Registration Review at 84.

17. In their opening remedy brief, Plaintiffs initially request that the Court find that the "may affect" threshold has been met and that EPA should therefore be ordered to consult immediately. Plaintiffs' Opening Remedy Brief at 9-10. As outlined in paragraphs 12-16 above, EPA has not completed effects determinations to date for the subject clothianidin and thiamethoxam actions, and absent such determinations, there is an insufficient basis to support the development of Service biological opinions. Alternatively, Plaintiffs ask the Court to order EPA to begin consultation within 180 days from the Court's Order. Id. at 24. That timeframe fails to account for the complexity of assessing the dozens of approved uses for these pesticides across the country and as explained in the following paragraphs, it fails to account for EPA's available resources to complete such assessments.

18. EPA's available resources to complete BEs for the 59 agency decisions at issue in this case regarding various products containing thiamethoxam and clothianidin are currently limited by competing obligations arising from settlement agreements binding on EPA and/or the Services. As noted in paragraph 11, EPA is currently engaged with both Services on

nationwide consultations to support the FIFRA registration review of products containing chlorpyrifos, diazinon and malathion. While EPA initiated those consultations in January 2017, at this point EPA's consultation with FWS has not been completed and FWS has reached out to the parties in the settlement agreement directing that consultation in order to seek more time beyond the December 31, 2017 compliance date to complete that initial pilot consultation.[2] Although that request has not been resolved, EPA will need to commit additional resources to that consultation before it is completed. Indeed, FWS has recently requested that EPA provide additional use and usage information about the three pilot pesticides to support these initial nationwide consultations and EPA has indicated it anticipates that compiling and analyzing that information will take approximately six months. See Exhibit 2 (November 2017 letter exchange between FWS and EPA). But more significantly, as noted, EPA has also committed to complete six additional nationwide BEs on products containing the pesticides carbaryl, methomyl, atrazine, simazine, propazine and glyphosate over the next two and one-half years. EPA's commitment regarding carbaryl and methomyl arises from CBD v. FWS, No. 3:11-cv-5108-JSW (N.D. Cal, Stipulation Amending Original Stipulated Settlement, July 28, 2014), a case to which EPA was a party. In order for FWS to fulfill its commitment to complete consultation on products containing carbaryl and methomyl by the settlement deadline of December 31, 2018, EPA must complete BEs to initiate those consultations in advance of that date. With respect to atrazine, simazine, propazine and glyphosate, in CBD v. EPA, No. 07-2794 (N.D. Cal, Stipulation Amending Original Stipulated Settlement, July 21, 2015), EPA is subject to a settlement agreement that requires EPA to complete nationwide BEs for products containing these pesticides by June 30, 2020. [3]

---

[2] On December 29, 2017, NMFS issued a final biological opinion for chlorpyrifos, diazinon, and malathion. This opinion represents the first completed consultation with either Service under the developing interim approaches.

[3] In both cases cited in this paragraph, FWS and EPA could, within the framework of those settlements, seek to revert to the original terms of these agreements requiring completion of certain regional-level ESA assessments. To date, EPA and FWS have not done so nor have the plaintiffs in those cases indicated to date that they would prefer EPA and FWS not complete the nationwide pilot consultations. Putting aside whether seeking such a result would represent good policy, it is unclear, at this point, that reverting to those original obligations would result in any meaningful resource savings for the government even if FWS and EPA were inclined seek relief from the terms of those amended agreements. Specifically, while the scope of the regional

19. In addition to these commitments, my staff also must conduct other ESA assessments to support OPP pesticide registration activities. While the matters I have mentioned above make up the largest portion of OPP's current ESA work, EFED is also engaged in developing BEs for new pesticide products registered for use on genetically modified crops and working to help defend litigation associated with the approval of such products.[4]

20. In light of EPA's current ESA obligations identified above, EPA reasonably expects that it will not be in a position to commence work on BEs for products containing clothianidin and thiamethoxam at least until it completes the June 30, 2020 BEs. Based on the work we have completed to date for chlorpyrifos, diazinon and malathion, EFED expects the total resources necessary to complete the next six nationwide BEs to exceed 15 full-time equivalents. This represents virtually all of the resources EFED has available to commit to endangered species work. Given that additional work will likely need to be done to complete consultation on chlorpyrifos, diazinon and malathion during this period, that additional methods will need to be developed for the first herbicides subjected to the interim methods, and given the additional work my office is doing to support the registration of products on genetically modified crops, I do not anticipate that EFED will have any available resources to commit to completing BEs for clothianidin and thiamethoxam prior to June 30, 2020.[5]

---

consultations would plainly be much smaller than a nationwide assessment, EPA and the Services are at this point three years into conducting national-level consultations. Abandoning that work and revisiting regional consultations that EPA commenced several years ago would likely come with considerable resource implications.

[4] EPA currently is in litigation regarding two such approvals: National Family Farm Coalition, et al. v. EPA (9th Circuit 17-70196) (Petition for Review on Dicamba Registration) and National Family Farm Coalition, et al. v. EPA (9th Circuit 17-70810) (Petition for Review of Enlist Duo Registration).

[5] EFED's work under the Endangered Species Act must also compete with other significant work EFED must undertake in order for EPA to comply with the requirements of FIFRA. Specifically, my office also conducts ecological risk assessments and drinking water exposure assessments that support new registration actions under section 3(c) of FIFRA and the registration review of existing pesticides under section 3(g) of FIFRA. These activities take up the large majority of EFED's available resources. Because these activities are subject to statutory deadlines, taking staff off these activities in order to complete BEs for clothianidin and thiamethoxam would force EPA to risk missing deadlines for new product registrations under section 33 of FIFRA and further challenge EPA's efforts to meet the October 1, 2022 deadline

21. Once EPA completes the June 30, 2020 BEs, EPA estimates that it will be able to complete BEs for products containing clothianidin and thiamethoxam products within two years, or June 2022. This estimate is based on EPA's recent experience in developing BEs for chlorpyrifos, diazinon and malathion. Once the interim approaches were first developed in November 2013, EPA needed approximately three years to complete BEs for products containing those pesticides. The complexity of this exercise cannot be overstated. As noted, these BEs each exceeded 10,000 pages in length and EPA received over 70,000 public comments when it issued draft BEs in April 2016 for public comment. While EPA expects that it will have achieved some efficiencies under the interim approaches by the time it starts the clothianidin and thiamethoxam assessments, neonicotinoid pesticides are the most widely used insecticide products (by acreage) in the United States and therefore determining the extent and nature of overlap with listed species and habitat as part of steps 1 and 2 will be a substantial undertaking that is likely equal in magnitude to the work done for chlorpyrifos, diazinon and malathion. EPA has discussed this matter with the Services and they are aware of EPA's estimated schedule to make effects determinations and initiate consultation on these product decisions and these two active ingredients more generally. Neither of the Services requested that EPA initiate formal consultation at an earlier date.

22. The estimate provided in paragraph 21 comes with significant uncertainty given the large number of ESA judicial challenges to EPA's FIFRA actions that the agency currently faces. In addition to the present case and the two cases identified in footnote 2, EPA currently is also defending seven other ESA cases involving pesticides.[6] The assumption in paragraph 21 that EPA can complete BEs for clothianidin and thiamethoxam between June 30, 2020 and

---

for completing registration review of all products containing over 700 pesticide active ingredients under section 3(g) of FIFRA.

[6] See Center for Biological Diversity, et al. v. EPA (N.D. Ca. 3:11cv293); Center for Biological Diversity, et al. v. EPA, No. 15-1054 (D.C. Cir.) (flupyradifurone); Center for Biological Diversity, et al. v EPA, No. 15-1176 (D.C. Cir.) (bicylcopyrone); Center for Biological Diversity v. EPA, No. 15-1389 (D.C. Cir.) (benzovindiflupyr); Center for Biological Diversity v. EPA, No. 15-1462 (D.C. Cir.) (cuprous iodide); Center for Biological Diversity v. EPA, No. 16-1351 (D.C. Cir.) (halauxifen-methyl); and NRDC v EPA (D.D.C. 1:17-cv-02034) (acetamiprid, dinotefuran, and imidacloprid).

June 2022 is predicated on these other courts not imposing significant consultation-related deadlines during that timeframe. Should that not be the case, EPA would likely need additional time beyond the estimate provided above to complete BEs for the clothianidin and thiamethoxam actions at issue in this matter.

23. EPA's timeframe provided above is also based on the premise that the most efficient and comprehensive approach for addressing an Order to consult on the 59 subject actions is to complete the BEs in connection with EPA's currently ongoing registration reviews of clothianidin and thiamethoxam under section 3(g) of FIFRA. What that means is that while any order the Court issues may be limited to roughly half of all thiamethoxam and clothianidin products currently on the market (there are over 100 currently registered products containing these ingredients), given EPA's present obligation to review all products and uses of these pesticides nationwide, it would be more efficient for EPA to develop BEs addressing the broader registration review of these pesticides rather than complete what would be a "piecemeal" BEs on just the 59 product actions in this case. While it is not clear from Plaintiffs' brief whether they might share that view, their requested 180-day timeframe for completing BEs is insufficient to complete a "piecemeal" assessment, much less an assessment of all uses nationwide in the course of registration review. In any case, conducting Biological Evaluations that are limited in scope -- either limited in the number of products, uses, or species -- would be inefficient and ultimately result in EPA conducting multiple assessments, public comment periods, and negotiations of potential risk reduction measures with pesticide registrants (should EPA conclude that such actions are necessary). It could also lead to inconsistencies in the data available and methods used to conduct the evaluations as the assessment processes continue to evolve and data continue to be developed in the research community. Also, the time and resource savings of conducting narrower evaluations are unclear. The 59 actions at issue encompass the majority of approved uses for these pesticides. Therefore, depending on how use of these products compares with products unaffected by this litigation, compiling and evaluating chemical-specific fate and ecotoxicity data would likely still need to occur and multiple aquatic and terrestrial environments would likely still need be considered and modeled. Therefore, any short-term resource savings realized by limiting the scope of the assessment would likely be minimal and would result in the need to conduct

multiple assessments, which would likely result in longer-term increases in resource expenditures.

24. It is also important to note that the interim approaches implementing the NAS recommendations are expected to continue to evolve as EPA and the Services conduct consultations on the pesticides that are currently serving as the pilot consultations for those new methodologies. Proceeding with a piecemeal consultation – which is all that EPA could attempt to do under the timeframe Plaintiffs seek -- may require EPA to prepare supplemental and potentially superseding analyses later when EPA completes work on these pesticides. For example, as noted in paragraph 18, FWS recently requested use and usage data for the first three pilot chemicals (chlorpyrifos, diazinon and malathion) to incorporate into their development of a biological opinion for those pesticides. Similarly, we also expect that additional refinements in species location and range data will continue to occur as we develop the pilots. If EPA proceeds with the clothianidin and thiamethoxam BEs on the schedule sought by Plaintiffs, the agency will effectively be forced to forego incorporating pilot process developments into its assessments, giving rise to the possible need to develop en entirely revised analysis when EPA completes its registration review assessment of these pesticides.

25. As noted, these chemicals are currently proceeding through the registration review program under section 3(g) of FIFRA. Under the program, EPA must determine whether pesticides containing any of over 700 active ingredients (including clothianidin and thiamethoxam) will present "unreasonable adverse effects on the environment" (the FIFRA standard as defined in section 2(bb) of FIFRA, 7 U.S.C. section 136(bb), that applies to EPA review of new pesticides as well as the registration review of existing pesticides). It is possible that in the course of registration review, the approved uses and use directions of clothianidin and thiamethoxam products may be modified to address risk concerns identified in that process. For this reason, EPA believes it would be more efficient for EPA to complete BEs as part of the registration review process, thereby taking account of any registration modifications that may occur in the course of registration review.

26. The 180-day timeframe Plaintiffs seek would also likely compel EPA to forego any opportunity for public process in the development of the BEs. When EPA issued its draft registration review biological evaluations in April, 2016 for chlorpyrifos, diazinon and

malathion, EPA received comments from over 70,000 individuals (which included pesticide registrants, growers, food processors, environmental organizations, academics, various governmental entities as well as unaffiliated members of the public). These included approximately 120 comments raising highly detailed scientific analysis requiring significant EFED review and resulting in certain modifications to EPA's BEs. EPA would similarly expect to receive high levels of public interest on draft BEs for clothianidin and thiamethoxam and would expect to receive comments that would lead to significant refinements of the BEs, thereby improving the accuracy of EPA's assessment and providing a better basis for conducting consultation with the Services. Given the several months it takes, however, to conduct a meaningful notice and comment process, EPA would likely not be able to engage the public on its draft BEs were it to be ordered to complete effects determinations within 180 days, as requested by Plaintiffs.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct. Executed on this 4th day of January, 2018.

Marietta Echeverria

Marietta Echeverria
Director, Environmental Fate and Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

United States Department of the Interior

FISH AND WILDLIFE SERVICE
Washington, D.C. 20240

In Reply Refer To:
FWS/AES/DCHRS/039744 JAN 14 2009

Arthur-Jean B. Williams, Associate Director
Environmental Fate and Effects Division
Office of Pesticide Programs (7507P)
U.S. Environmental Protection Agency
Washington, DC 20460

RE: Request for Initiation of Formal Consultation on the Effects of Reregistration of pesticides

Dear Ms. Williams:

This letter acknowledges the U.S. Fish and Wildlife Service's (Service) receipt of your letters requesting initiation of formal section 7 consultation under the Endangered Species Act of 1973, as amended (ESA)(see attachment). These consultations concern the possible effects of the Environmental Protection Agency's (EPA) reregistration of pesticides on federally threatened and endangered species and their critical habitats.

The Service has not received all of the information necessary to initiate formal consultation on the reregistration of these pesticides as outlined in the regulations governing interagency consultation (50 CFR §402.14). To complete the initiation packages, additional information, described below, will be required for each consultation request. For a more detailed discussion on the missing information, please refer to our February 11, 2008, letter responding to your consultation request on the effects of atrazine on the Alabama sturgeon (*Scaphirhynchus suttkusi*) and dwarf wedgemussel (*Alasmidonta heterodon*).

1. A full description of the action to be considered. During our interagency meetings of December 10-12, we recall reaching a consensus that the proposed action included EPA's reregistration of pesticide products and approval of labels. To fulfill this requirement, we request that EPA submit a list of all current product registrations for which consultation is being requested (including associated labels defining product uses where available), the ingredients contained therein, the other ingredients in recommended tank mixtures, and any known toxicity data for these chemicals for consultation requests received both prior and subsequent to these meetings.

2. A complete description of the manner in which the action may affect the listed species and their critical habitats, including an exposure analysis that represents reasonable worst

TAKE PRIDE IN AMERICA

case scenarios for both the entire action area and for individual portions of the action area relevant to the listed species and designated critical habitats under consultation. In informal consultation, we determine whether listed species or critical habitats are likely to be adversely affected and would base the determination upon the most extreme exposure concentration that could occur to any individuals or critical habitats in the action area. This enables the Service to assist the action agency in complying with not only section 7 of the ESA, but also the section 9 prohibitions on "take." This extreme exposure estimate typically would not be expected to occur uniformly across the range of a listed species or its critical habitat because, for example, the percentage of watersheds dedicated to cropland will vary. For a formal consultation, a reasonable worst-case analysis would characterize the extreme range of exposures likely to occur to the various populations of the listed species or units of critical habitat, or portions thereof. This latter analysis would allow us to characterize the proportion of the species range or critical habitat exposed to the highest concentrations of pesticides, and the proportion exposed to more moderate concentrations.

3. An estimate of existing and future pollutant loads in the action area as a basis for determining whether listed species are likely to be adversely affected by the addition of the pesticide products and, if so, an analysis of the extent of effects over the reregistration period. The Service and NOAA are developing methods for weighing the influence and effects of "environmental mixtures." EPA may choose to await development of these approaches, or adopt their own methods for considering existing environmental conditions that influence the manner in which the action may affect listed species or critical habitat.

We will be unable to fully evaluate the effects of this action or formulate a biological opinion until we receive all of this information.

While EPA is preparing this information, the Service will continue to engage in informal consultation with you on these and other reregistration actions. At our interagency meetings of December 10-12, 2007, our agencies committed to working together in the development of methodologies to fulfill EPA's section 7 requirements for pesticide registration activities. We believe a more collaborative, team-oriented approach would benefit EPA in submitting consultation requests that include all of the information necessary to complete section 7 consultations. Specifically, we agreed work jointly to:

- modify existing modeling to ensure estimated environmental concentrations (EECs) represent worst-case scenario concentrations as a basis for making effects determinations;
- modify existing modeling to ensure EECs are adequately predicted in low-flow and off-channel habitats;
- develop methodology to account for future changes in use of pesticides (at least 15 years) in urban and residential settings;
- identify and develop exposure estimates required for an effects analysis for formal consultation;

- develop an approach for modeling EECs on a nationwide scale for Section 3 Registration Review ;
- develop a methodology to adequately account for exposure to additional chemical ingredients in formulated products and environmental mixtures; and,
- develop a methodology to incorporate information on sublethal effects in making Not Likely to Adversely Affect/Likely to Adversely Affect determination.

Finally, we note that the volume and complexity of EPA's section 7 consultation requests on pesticide reregistrations exceed our capability to complete consultations within normal statutory timelines. We would be happy to continue to discuss with EPA ways in which to best utilize our joint resources to address EPA's consultation workload, including establishing priorities and realistic timelines given the Service's limited staff resources.

We look forward to meeting with your staff to jointly pursue solutions to these complex issues that will meet the standards of the Endangered Species Act. If you have any questions or concerns about this consultation or the consultation process in general, please feel free to contact Nancy Golden (703-358-2148; Nancy_Golden@fws.gov) or Dan Buford (703-358-2106; Daniel_Buford@fws.gov) of my staff.

Sincerely,

Marjorie A. Nelson, Chief
Branch of Consultation & HCPs
Division of Consultation, Habitat Conservation Planning, Recovery and State Grants

Enclosure

Enclosure 1. Consultation requests received from EPA for pesticide registration activities:

Date request received	Action
March 14, 2007	Approval of products containing the active ingredient atrazine, and effects on seven federally listed endangered freshwater mussels: Pink Mucket Pearly (*Lampsilis abrupta*) Rough Pigtoe (*Pleurobema plenum*) Shiny Pigtoe Pearly (*Fusconaia edgariana*) Fine-rayed Pigtoe (*Fusconaia cuneolus*) Heavy Pigtoe (*Pleurobema taitianum*) Ovate Clubshell (*Pleurobema perovatum*) Southern Clubshell (*Pleurobema decisum*)
July 22, 2007	Approval of products containing the active ingredients acephate, aldicarb, azinphos methyl, chloropicrin, diazinon, imazapyr, metam sodium, methamidiphos, methomyl, metolachlor and effects on the red-legged frog *(Rana aurora draytonii)*
September 17, 2007	Approval of products containing the active ingredient atrazine, and effects on the pallid sturgeon (*Scaphirhynchus albus*)
September 17, 2007	Approval of products containing the active ingredient atrazine, and effects on the Topeka shiner (*Notropis topeka*
September 17, 2007	Approval of products containing the active ingredient atrazine, and effects on the fat pocketbook pearlymussel (*Potamilus capax*), northern riffleshell (*Epioblasma torulosa rangiana*), and purple cat's paw pearlymussel (*Epioblasma obliquata obliquata)*
September 21, 2007	Approval of products containing the active ingredient prometon, and effects on the Barton Springs Salamander *(Eurycea sosorum)*
September 21, 2007	Approval of products containing the active ingredient carbaryl, and effects on the Barton Springs salamander *(Eurycea sosorum)*
October 22, 2007	Approval of products containing the active ingredients simazine, oxydemeton methyl, mancozeb, maneb, chlorothalonil, bromacil, bensulide, carbaryl, malathion, captan and effects on the red-legged frog *(Rana aurora draytonii)*
Febraury 20, 2008	Approval of products containing the active ingredients methyl parathion, propyzamide, naled, S-methoprene, dimethoate, esfenvalerate, hexazinone and effects on the red-legged frog *(Rana aurora draytonii)*

June 20, 2008	Approval of products containing the active ingredients EPTC, disulfoton, linuron, telone, phosmet, propargite and Oryzalin and effects on the red-legged frog *(Rana aurora draytonii)*
October 20, 2008	Approval of products containing the active ingredients glyphosate, oxyfluorfen, permethrin, phorate, rotenone, tribufos, ziram, and effects on the red-legged frog *(Rana aurora draytonii)*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 17 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Gary Frazer
Assistant Director
U.S. Fish and Wildlife Service
Ecological Services
5275 Leesburg Pike
Falls Church, VA 22041-3803

Dear Mr. Frazer,

Thank you for your letter requesting additional information to complete formal consultation on the Biological Evaluations (BEs) for chlorpyrifos, malathion, and diazinon, which were finalized on January 18, 2017.

As you are aware, the BEs were developed with Services oversight and included all information and analyses as requested by the National Marine Fisheries Service (NMFS) and Fish and Wildlife Service (FWS) during their development. We understand, however, that in the course of our consultation, FWS has indicated that additional information regarding use and usage information could be of value in the development of the FWS biological opinions (BiOps). We will treat your letter as a request for additional information as described in section 402.14(f) of the FWS regulations and not a request to revise the EPA BEs with additional information under section 402.46(b). This is consistent with the regulations that require requests from FWS for additional information to be submitted within 45 days of EPA providing the BE to FWS (50 CFR Part 402). Accordingly, any agreement from EPA to supplement the consultation should not be viewed as EPA's agreement to either revise or withdraw its final BEs.

We are pleased that the utility of the use and usage information is being reconsidered, and we anticipate being able to provide this information within approximately 6 months.
Use information (*e.g.*, maximum application rate, number of allowed applications, etc.) is extracted directly from product labels whereas usage information describes where, when, and how a pesticide is actually being used based on survey information. In order to provide the requested use and usage information, staff from EPA's Biological and Economic Analysis Division (BEAD) must compile and summarize label information, appropriately aggregate complex use directions, and develop associated usage statistics. The number of registered use sites for these active ingredients is extensive with more than 100 active registered products for

chlorpyrifos and diazinon. Additionally, this work would need to be completed concurrently with BEAD's existing workload to provide use and usage information supporting EPA's registration review program.

Your letter also requests to extend the consultation in accordance with 50 C.F.R.402.14(e). We agree that consultation should continue and be extended as necessary, and that any required consent from any applicants be obtained.

Sincerely,

Brian J. Anderson

For Marietta Echeverria
Director, Environmental Fate and Effects Division
Office of Pesticide Programs

United States Department of the Interior

FISH AND WILDLIFE SERVICE

NOV 14 2017

Marietta Echeverria
Director, Environmental Fate and Effects Division
Office of Pesticide Programs
Division Mail Code 7507P
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Dear Ms. Echeverria,

On January 18, 2017, the U.S. Fish and Wildlife Service (Service) received the Environmental Protection Agency's (EPA) draft Biological Evaluations (BEs) on the effects of reregistering chlorpyrifos, malathion, and diazinon under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and request to initiate formal consultation under section 7 of the Endangered Species Act of 1973, as amended (ESA). As you are aware, this effort was one of the most complex section 7 consultations ever attempted. While we appreciate the collaboration with the Service and others that informed the development of these BEs, after further review and lessons learned in consideration of the BEs the Service is requesting additional information necessary to complete formal consultation. (See interagency consultation regulations at 50 CFR §402.14). Specifically, we request:

- A revised effects analysis for each chemical that reflects the best scientific and commercial data that is currently available or which can be obtained during the consultation – the standard for information required under 50 CFR §402.14(d) for an action agency when seeking formal consultation – regarding actual use, including extrapolation to areas where actual use data does not exist or cannot be obtained. The revised effect analyses should also seek to predict effects from future usage that is reasonably certain to occur during the time period of the label authorization but is not reflected in current actual use data.

- A revised effects analysis for each chemical that eliminates from analysis geographic areas identified by EPA where these pesticides are not used and where such use is not likely during the time period of the label authorization, or where listed species or designated critical habitats would not otherwise be exposed to use of the pesticide (e.g., certain states, high elevation areas, uninhabited islands).

In addition, the Service also suggests that the EPA monitor available use and usage information to determine if the manner of actual use remains consistent with assumptions of use and usage considered in the consultation process.

Under the regulations, indirect effects are "those that are caused by the proposed action and are later in time, but are reasonably certain to occur." 50 C.F.R. 402.02. The effects analysis determines the action area, which is "all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action." 50 C.F.R. 402.02. We must keep in mind the ESA regulations when considering the action description and effects analysis.

In the course of developing the draft and final biological opinions and associated incidental take statements, the Service requests that EPA facilitate coordination with the registrants and user groups to develop, if necessary, any reasonable and prudent alternatives to avoid violation of section 7(a)(2) of the Act and any reasonable and prudent measures necessary or appropriate to minimize the impact of your action on listed species.

This letter also serves as a request to extend the consultation, in accordance with 50 C.F.R. 402.14(e). Upon receipt of the above requested information, the Service will work with EPA to establish a schedule to complete consultation on the proposed actions.

If you have any questions or concerns about this request or the consultation process in general, please feel free to call me at 202-208-4646 or Deputy Assistant Director Gina Shultz at 703-358-1985.

Sincerely,

Gary Frazer
Assistant Director - Ecological Services